IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF UTAH

XLEAR, INC., a Utah corporation, Plaintiff,	MEMORANDUM DECISION AND ORDER DENYING [64] MOTION FOR SUMMARY JUDGMENT
v.	Case No. 2:14-cv-00806-DN
STS HEALTH, LLC, a Virginia Limited Liability Company,	District Judge David Nuffer
Defendant.	

Defendant STS Health, LLC ("STS") filed a Motion for Summary Judgment (the "Motion"). STS argues in the Motion that the asserted patent claims of U.S. Patent No. 6,054,143 ("143 patent") are invalid under 35 U.S.C. §101 ("§101") as they fail to recite patent-eligible subject matter. Plaintiff Xlear, Inc. ("XLEAR") disagrees and opposed the Motion for Summary Judgment. STS replied in support. For the reasons stated below, the Motion for Summary Judgment is DENIED.

BACKGROUND

This is not the first time that STS has argued patent ineligibility under § 101. In April 2015, STS filed a motion to dismiss XLEAR's complaint for failure to state a claim.⁵ STS

³ Plaintiff's Memorandum in Opposition to Defendant's Motion for Summary Judgment ("Opposition"), <u>docket no.</u> 73, filed Mar. 31, 2017.

¹ Defendant's Motion for Summary Judgment and Memorandum in Support ("Motion for Summary Judgment"), docket no. 64, filed Feb. 28, 2017.

² *Id*. at 1

⁴ Defendant's Reply in Further Support of its motion for Summary Judgment ("Reply"), <u>docket no. 80</u>, filed Apr 14, 2017.

⁵ Defendant STS Health, LLC's Motion to Dismiss Plaintiff Xlear, Inc.'s First Amended Complaint under Fed. R. Civ. P. 12(b)(6) and Memorandum in Support, <u>docket no. 29</u>, filed April 13, 2015.

argued that the '143 patent was invalid under 35 U.S.C. § 101 for being directed at patent ineligible subject matter. STS contended that XLEAR was simply describing the naturally occurring product xylitol and then teaching its application by "well-understood, routine, conventional activity previously engaged in by the researchers in the field." XLEAR argued that the '143 patent method claim provides "a way for xylitol/xylose to be more efficiently introduced to the nasopharynx through nasal administration, reducing bacteria in that area and subsequently reducing the occurrence of infections associated with those bacteria."

STS's motion as to § 101 was denied ("Previous Order")⁹ after applying the two-step framework laid out by the United States Supreme Court in *Alice Corp. Pty. Ltd. v. CLS Bank Int'l* (the "*Alice* Framework"). ¹⁰ Under the first step of the *Alice* Framework, the '143 patent was found not to claim the naturally occurring product xylitol/xylose, but instead to claim a *method for delivery* of the xylitol/xylose to clean out the nasopharynx in a human. ¹¹ The analysis in the Previous Order then continued to the second step of the *Alice* Framework. At this juncture, despite STS's argument that the use of nasal spray to deliver xylitol/xylose was "well-understood, routine, conventional," the Previous Order stated that evidence "is needed to know if the nasal solutions were in fact pre-existing or if there were any similar application of xylitol prior to the '143 patent that render" it non-novel. STS did not present this evidence in its motion

⁶ *Id*. at 1.

⁷ Defendant STS Health, LLC's Reply Brief to Plaintiff's Memorandum in Opposition to Defendant's Motion to Dismiss the First Amended Complaint under Fed. R. Civ. P. 12(b)(6) at 6, <u>docket no. 33</u>, filed June 16, 2015 (quoting *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 72 (2012)).

⁸ Plaintiff's Memorandum in Opposition to Defendant's Motion to Dismiss the First Amended Complaint under Fed. R. Civ. P. 12(b)(6) at 9, <u>docket no. 31</u>, filed May 26, 2015.

⁹ Memorandum Decision and Order Denying Motion to Dismiss ("Previous Order") at 12, <u>docket no. 31</u>, filed Dec. 15, 2015.

¹⁰ 573 U.S. 208, 217 (2014).

¹¹ Previous Order at 10.

to dismiss. And because the analysis of a motion to dismiss required that XLEAR's factual allegation—that the '143 patent's application of xylitol/xylose was novel—be accepted as true, the motion to dismiss was denied.¹²

In response to the question posed in the Previous Order regarding the evidence needed at the second Alice Framework step, STS now presents in its Motion for Summary Judgment seven issued patents as evidence that the nasal administration of xylitol/xylose was well-known, conventional, and routine when the patentee applied for the '143 patent. ¹³ Each of these patents has a priority date before the '143 patent's priority date. In further support of this argument, STS also presented a table pointing out where each of the patents mention xylitol/xylose, saline solutions, and nasal administration of the solution. ¹⁴

LEGAL STANDARD—SUMMARY JUDGMENT DUE TO INVALIDITY

Summary judgment is appropriate if "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." A factual dispute is genuine when "there is sufficient evidence on each side so that a rational trier of fact could resolve the issue either way." In determining whether there is a genuine dispute as to material fact, the court should "view the factual record and draw all reasonable inferences therefrom most favorably to the nonmovant."

¹² *Id.* at 12.

¹³ Motion for Summary Judgement at 9–10.

¹⁴ *Id*.

¹⁵ Fed. R. Civ. P. 56(a).

¹⁶ Adler v. Wal-Mart Stores, Inc., 144 F.3d 664, 670 (10th Cir. 1998).

¹⁷ *Id*.

The moving party "bears the initial burden of making a prima facie demonstration of the absence of a genuine issue of material fact and entitlement to judgment as a matter of law." ¹⁸ 35 U.S.C. § 282 establishes a presumption of validity for granted patents. ¹⁹ "The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity." ²⁰ In an argument for invalidity, any fact "that is pertinent to the invalidity conclusion must be proven by clear and convincing evidence." ²¹

DISCUSSION

In order to determine whether a patent is invalid under § 101, The United States Supreme Court laid out the two-step *Alice* Framework for "distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts." The first step under the *Alice* Framework is to "determine whether the claims at issue are directed to one of those patent-ineligible concepts." If so, the next step is to determine if there are additional elements that "transform the nature of the claim into a patent-eligible application." A valid patent must be "significantly more" than a patent upon the ineligible concept itself. If under step one, it is determined that the claims are not directed to patent ineligible subject matter, then there is no need to continue the analysis to step two.

¹⁸ *Id.* at 670–71.

¹⁹ 35 U.S.C. § 282.

²⁰ *Id*.

²¹ Berkheimer v. HP, Inc., 881 F.3d 1360, 1368 (Fed. Cir. 2018).

²² Alice Corp. Ptv. Ltd. v. CLS Bank Int'l, 573 U.S. 208, 217 (2014).

²³ *Id*.

²⁴ *Id*.

²⁵ *Id*.

The '143 Patent Does Not Point to Patent Ineligible Subject Matter

The Previous Order determined that under step one of the Alice Framework, "the '143 patent claims a process or method which is not a law of nature or natural phenomenon[.]" ²⁶ Specifically the Previous Order determined that the '143 patent does not claim the discovery of xylitol/xylose or the product itself. It also does not claim the exclusive right to every application of xylitol/xylose. The patent claims focus on the process of practically applying xylitol/xylose to clean the nasopharynx. ²⁷

Because it was determined that the claims do not point to an ineligible subject matter, it was unnecessary to proceed to the second step and determine "whether additional elements 'transform[ed] the nature of the claims' into a patent-eligible application." The analysis in the Previous Order should have stopped after concluding that the claims of the '143 patent do not point to patent ineligible subject matter. The Previous Order should not have stated that additional evidence was needed to resolve the second step of the *Alice* Framework.

But even if it were necessary to analyze the '143 patent under step two of the *Alice*Framework, STS has not carried its burden under that step. "Whether a claim recites patent eligible subject matter is a question of law which may contain disputes over underlying facts." Step two of the Alice Framework is satisfied when "the additional elements [that] transform the nature of the claim into a patent eligible application . . . involve more than performance of well-understood, routine, [and] conventional activities previously known to the industry." When a

²⁶ Memorandum Decision and Order denying motion to dismiss at 12, docket no. 37, filed Dec. 15, 2015.

²⁷ Memorandum Decision and Order Regarding Claim Construction, <u>docket no. 85</u>, filed Apr. 4, 2019.

²⁸ *Alice* at 217.

²⁹ Berkheimer at 1368.

³⁰ *Id.* at 1367 (internal citations omitted).

party argues invalidity under § 101, summary judgment is appropriate where "there is no genuine issue of material fact regarding whether the claim element ... is well-understood, routine, [or] conventional to a skilled artisan in the relevant field."³¹

In the Motion for Summary Judgment, STS presents seven U.S. patents issued before the '143 patent, and points to language in each of them that recites phrases related to the asserted claims. 32 STS argues that the language in these patents show that the nasal administration of xylitol/xylose was conventional at the time of the '143 patent's application. 33

However, the Federal Circuit has stated that whether "something is well-understood, routine, or conventional to a skilled artisan at the time of the patent is a factual determination" and "goes beyond what was simply known in the prior art."³⁴ In this factual determination, prior art is probative but not determinative that the '143 patent is ineligible under § 101. STS has not shown how the seven cited patents teach the same invention as the '143. The seven cited patents address the use of xylitol/xylose to aid in the absorption of other compounds through mucosal membranes, such as that found in the nose.³⁵ None of the cited patents address using xylitol/xylose to clean the nasopharynx.

Further, Xlear still contends that nasal administration of xylose/xylitol for cleaning the nasopharynx in a human was not conventional at the time of application.³⁶ The seven cited patents do not disprove that contention and STS has not demonstrated the absence of an

³¹ *Id.* at 1368.

³² Motion for Summary Judgement at 9–10.

³³ *Id*.

³⁴Berkheimer at 1369.

³⁵ See U.S. Patent No. 5,482,706, U.S. Patent No. 5,578,567, U.S. Patent No. 6,024,066, U.S. Patent No. 5,514,673, U.S. Patent No. 5,858,410, U.S. Patent No. 5,785,976, U.S. Patent No. 5,411,993.

³⁶ Opposition at 15.

underlying genuine issue of material fact that would permit deciding patent eligibility "on summary judgment as a matter of law."³⁷

35 U.S.C. §§ 102 and 103

The briefing from the parties also mention invalidity under 35 U.S.C. §§ 102 and 103. XLEAR argues that STS, by citing patents that allegedly contain each element of the '143 patent claims, is mixing up the § 101 ineligibility argument with a § 103 obviousness argument. STS responds and contends that the seven cited patents do demonstrate that the patent claims are invalid as anticipated under § 102. However, STS also recognizes that the present motion is solely directed to the asserted claims being patent ineligible under § 101. Because STS's motion does not seek relief under § 102 or 103, there is no need to discuss the seven cited patents under a § 102 or § 103 analysis at this time.

As the Previous Order determined under the first step of the Alice Framework, the claims of the '143 patent do not point to patent ineligible subject matter. The '143 Patent is therefore not invalid under § 101. But even if it had been necessary to analyze the claims of the '143 Patent under step two of the *Alice* Framework, STS has not met the high burden of showing by clear and convincing evidence that the '143 patent claims fail under this step. Summary judgment is not appropriate. The Motion is denied.

³⁷ See Berkheimer at 1368.

³⁸ *Id.* at 11.

³⁹ Reply at 8–9.

⁴⁰ *Id.* at 9.

ORDER

IT IS HEREBY ORDERED that STS's Motion for Summary Judgment⁴¹ is DENIED. Signed April 15, 2019.

BY THE COURT

David Nuffer

United States District Judge

⁴¹ Defendant's Motion for Summary Judgment and Memorandum in Support, <u>docket no. 64</u>, filed Feb. 28, 2017.